K100630 p.1 of 2

WRIGHT.

510(K) SUMMARY
OF SAFETY AND EFFECTIVENESS

JUN 11 2010

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CRF 807.92, this information serves as a Summary of Safety and Effectiveness for the use of the G-FORCE® Suture Anchor System.

Submitted By:	Wright Medical Technology, Inc.
Date:	March 3, 2010
Contact Person:	Kellen Hills
Title:	Sr. Regulatory Affairs Specialist
Address:	5677 Airline Road, Arlington TN 38002
Phone:	800.238.7117
Proprietary Name:	**G-FORCE® Suture Anchor System**
Common Name:	Soft Tissue Anchor
Classification Name and Reference:	21 CFR 888.3040 - Smooth or threaded metallic bone fixation fastener - Class II
Device Product Code and Panel Code:	Orthopedics/87/MBI/HWC
Predicate Device:	ANCHORLOK® Soft Tissue Anchor System (K971282)

DEVICE INFORMATION

A. DEVICE DESCRIPTION

The G-FORCE® Suture Anchor is a sterile, single-use, hand-held device intended to aid in the attachment of soft tissue to bone. The G-FORCE® Suture Anchor comes preloaded with non-absorbable polyethylene-based sutures, needles and PEEK-OPTIMA® anchors. The anchors are available in a variety of sizes with correspondingly sized suture.

B. INDICATIONS FOR USE

The G-FORCE® Suture Anchor System is indicated for use:

- In the repair of shoulder instability secondary to Bankart lesion, rotator cuff tear, a slap lesion, acromioclavicular separation, biceps tenodesis, deltoid tear/separation, or capsular shift or capsulolabral reconstruction;
- In the repair of elbow instability secondary to biceps tendon detachment, tennis elbow, or ulnar or radial collateral ligament tear/separation;

- In the repair of hand/wrist instability secondary to tear or separation of the scapholunate ligament, ulnar collateral ligament, or radial collateral ligament;
- In the repair of knee instability secondary to tear or separation of the medial collateral ligament, lateral collateral ligament, patellar tendon, or posterior oblique ligament, or secondary to iliotibial band tenodesis;
- In the repair of foot/ankle instability secondary to tear or separation of the Achilles tendon, lateral stabilization tendons/ligaments, medial stabilization tendons/ligaments, midfoot tendons/ligaments, or metatarsal tendons/ligaments.

C. SUBSTANTIAL EQUIVALENCE INFORMATION

The indications for use of the G-FORCE® Suture Anchor System are limited in scope when compared to the predicate. The technological characteristics by which the intended use is achieved is the same for both the subject and predicate systems.

The safety and effectiveness of the G-FORCE® Suture Anchor System are adequately supported by the substantial equivalence information, materials information, and analysis data provided within this 510(k).

Comparison of the G-FORCE® Suture Anchor and the predicate

	G-FORCE® Suture Anchor	ANCHORLOK® Soft Tissue Anchor System
Device	Subject Device	Predicate (K971282)
Implants Materials	Anchors: PEEK-OPTIMA® Sutures: Force Fiber™ (polyethylene based)	Anchors: Ti-6Al-4V Sutures: polyester
Anchor Diameters	3.5 and 5.0mm	1.9, 2.5, 3.5, 5.0 and 7.5mm
Suture Thickness	#2	2-0, 1-0 and #2
# of sutures	2 per anchor	1 per anchor
Needles	Tapered	Reverse cutting
Driver diameter	Consistent	Variable
Sterilization	Ethylene oxide gas	Gamma irradiation

D. PERFORMANCE DATA

Bench testing was used to demonstrate that the torque and tensile strength characteristics of the G-FORCE® Suture Anchor System are substantially equivalent to the predicate.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

Wright Medical Technology, Inc.
c/o Mr. Kellen Hills
Senior Regulatory Affairs Specialist
5677 Airline Road
Arlington, Tennessee 38002

JUN 11 2010

Re: K100630
Trade/Device Name: G-FORCE® Suture Anchor System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: MBI, HWC
Dated: June 7, 2010
Received: June 9, 2010

Dear Mr. Hills:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K100630

Device Name: G-FORCE® Suture Anchor System

Indications For Use:

The G-FORCE® Suture Anchor System is indicated for use:

- In the repair of shoulder instability secondary to Bankart lesion, rotator cuff tear, a slap lesion, acromioclavicular separation, biceps tenodesis, deltoid tear/separation, or capsular shift or capsulolabral reconstruction;
- In the repair of elbow instability secondary to biceps tendon detachment, tennis elbow, or ulnar or radial collateral ligament tear/separation;
- In the repair of hand/wrist instability secondary to tear or separation of the scapholunate ligament, ulnar collateral ligament, or radial collateral ligament;
- In the repair of knee instability secondary to tear or separation of the medial collateral ligament, lateral collateral ligament, patellar tendon, or posterior oblique ligament, or secondary to iliotibial band tenodesis;
- In the repair of foot/ankle instability secondary to tear or separation of the Achilles tendon, lateral stabilization tendons/ligaments, medial stabilization tendons/ligaments, midfoot tendons/ligaments, or metatarsal tendons/ligaments.

Prescription Use xxx AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K100630

Concurrence of CDRH, Office of Device Evaluation (ODE)